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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,987	06/26/2003	John R. Hawkins	DEP5118	6430

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EXAMINER

RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/608,987	HAWKINS, JOHN R.	
	Examiner	Art Unit	
	Anu Ramana	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11, 13-17, 19-20, 22-24 and 28-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11, 13-17, 19, 20, 22-24, 28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 11, 2005 has been entered.

Specification

The amendment filed April 11, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows: "at least one of the upper and lower surfaces of the outer shell comprises a recess for receiving a pin." The original disclosure only shows one surface (either upper or lower) having a recess. Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

Claim 19 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form.

Claim Rejections - 35 USC § 103

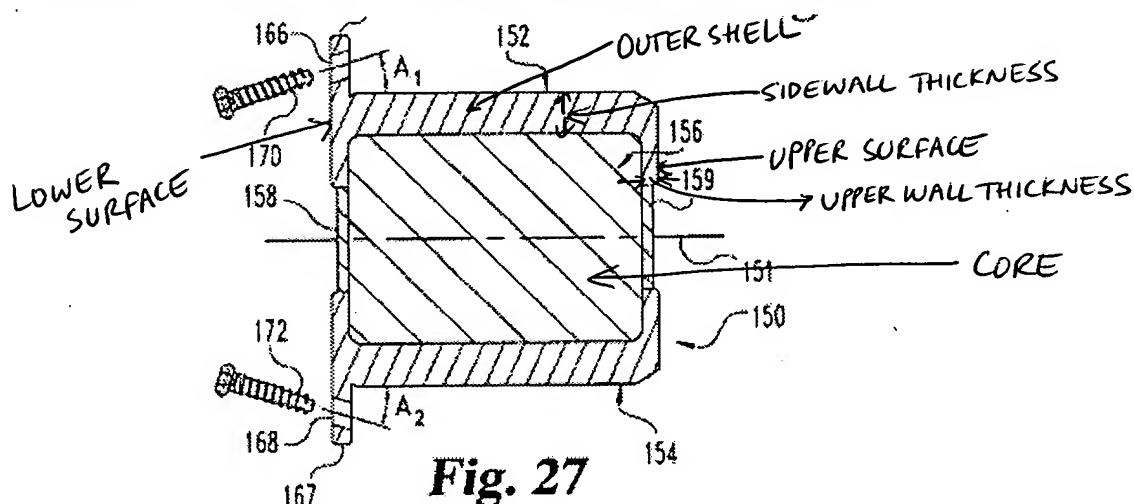
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8, 11, 14-17, 19, 20, 22-24, 28 and 29 under 35 U.S.C. 103(a) as being unpatentable over Zdeblick et al. (US 6,402,785) in view of Lawson et al. (US 6,802,863).

Zdeblick et al. disclose a disc implant having an outer shell 152 surrounding an elastic core 156 wherein a lower surface of the implant has a recess and a screw or "pin" 170 received in the recess (Figs. 25 and 27, col. 4, lines 65-67, col. 5, lines 1-14 and col. 9, lines 32-63). Also see marked up Fig. 27 below.



Zdeblick et al. disclose all elements of the claimed invention except for a coefficient of friction of at least 0.5.

Lawson et al. teaches providing a high coefficient of friction to a surface of an implant for immobility (col. 4, lines 34-37).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the Zdeblick et al. outer shell with a coefficient of friction of at least 0.5, as taught by Lawson et al., for immobility.

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Regarding claim 13, Zdeblick et al. disclose providing retention mechanisms such as interruptions, scales etc. to assist in retention and engagement of the implant with the vertebral bodies (col. 7, lines 10-26).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided roughness in a range of no more than 0.15 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Regarding claims 4 and 15, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the implant with an outer shell having convex upper and lower surfaces, since applicant has not disclosed that these shapes solve any stated problem or are anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of an implant. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Regarding claims 6 and 29, the thickness of the sidewall of the implant of the combination of Zdeblick et al. and Lawson et al. approximates a thickness of the annulus fibrosus. See marked up Fig. 27 on previous page.

Regarding claims 16, 22 and 23, Zdeblick et al. disclose that the outer shell can be made of materials such as titanium, polymers etc. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the implant of the combination of Zdeblick et al. and Lawson et al. of silicone, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zdeblick et al. (US 6,402,785) and Lawson et al. (US 6,802,863), as applied to claim 1, further in view of Parsons et al. (US 5,545,229).

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The combination of Zdeblick et al. and Lawson et al. disclose all elements of the claimed combination except for the presence of intermediate layers between the core and the outer shell.

Parsons et al. teach that the core of a prosthetic element may be reinforced (with intermediate layers).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided an intermediate layer in the core of the combination of Zdeblick et al. and Lawson et al., for reinforcement, as taught by Parsons et al.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zdeblick et al. (US 6,402,785) and Lawson et al. (US 6,802,863) further in view of Marino et al. (US 2004/0133278A1).

The combination of Zdeblick et al. and Lawson et al. disclose all elements of the claimed invention except for a radioopaque marker in the outer shell or core.

Marino et al. teach providing radiological or "radio opaque" markers in the components of an implant "invisible" to radiological techniques (para [0014]).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a radio opaque marker in the outer shell or core, as taught by Marino et al., in order to make the implant of the combination of Zdeblick et al. and Lawson et al. visible during radiologically assisted techniques such as implant insertion.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zdeblick et al. (US 6,402,785) and Lawson et al. (US 6,802,863) further in view of Joos (US 6,554,867).

The combination of Zdeblick et al. and Lawson et al. disclose all elements of the claimed invention except for roughness of no more than 0.15 mm.

It is well known to adjust the roughness of an implant for stability and osseointegration, as evidenced by Joos (col. 2, lines 8-30).

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Accordingly it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the implant of the combination of Zdeblick et al. and Lawson et al., with a roughness, as taught by Joos for stability and osseointegration. Further, it would have been obvious to have provided a roughness of no more than 0.15 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments with respect to claims 1-9, 11, 13-17, 19-20, 22-24 and 28-29 submitted under "REMARKS" in the response filed on April 11, 2005 have been considered but are moot in view of the new grounds of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR *Anuradha Ramana*
April 27, 2005


KEVIN SHAVER
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